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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,794	01/31/2002	Arthur L. Rosenthal	10177-101	3444

7590

08/23/2005

JONES DAY
222 East 41st Street
New York, NY 10017

EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,794

Applicant(s)

ROSENTHAL ET AL.

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: attached colored figure 6 2002/0068969.

DETAILED ACTION

1. Applicant's RCE dated 7/25/05 has been received in application serial number 10/062,794. claims 1-4 and 11-12 are pending in the application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Shanley 2002/0068969. Shanley discloses the invention as claimed (and for further clarity a color coded copy of figure 6 is enclosed) noting figure 6 comprising: A medical device (which is a stent 10) with a plurality of struts (***the strut region is interpreted to be sections 18 to 20***) and a plurality of non-structural elements (***this includes the region of element 14 and the material surrounding element 32***) integral with and projecting from the struts; ***and a coating comprising a biologically active material***

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disposed on the struts and the non-structural elements (this limitation is disclosed by Shanley in section [0038] "Alternatively, the beneficial agent for delivery to the lumen tissue may be coated on the device" and in section [0057]) wherein the struts (18 and 20) and the non-structural elements (14 and the material surrounding the opening 32) comprise the biologically active material [0038]; wherein the non-structural elements are configured in shapes including hoops and ovals.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley in view of Harish et al. 6,506,437. While Shanley does state the use of biologically active material, Shanley does not specify the drugs. Harish et al. teaches the use of paclitaxel, dexamethasone, and actinomycin (see col. 6, lines 64 and col. 7, lines 5 and 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the drugs of Harish et al. into the stent of Shanley because they could treat individual dysfunction at the tissue in the vessel site depending upon the individual patients needs.

Response to Arguments

6. Applicant's arguments filed 7/26/05 have been fully considered but they are not persuasive. Applicant continues to contends that Shanley does not disclose non-structural elements integral with and projecting from the struts and points out there definition of non-structural in the specification. Two definitions provided by the American heritage dictionary fourth edition are provided by the examiner (because no definition has been supplied by the specification of the application): 1. **strut** n: brace consisting of a bar or rod used to resist longitudinal compression; 2. **integral** a complete unit or whole; essential or necessary for completeness. According to these definitions and the broadest interpretation of the claims, the plurality of non-structural elements (which are elements 14 and the material surrounding the opening 32) of Shanley are "integral" with and projecting from the struts (which are sections 18-20) and meet the definition of non-structural as provided by applicants specification on page 8, lines 19-26 The curvature of 14 provides the "projection" away from the linear strut sections. Once again it is pointed out that Shanley discloses that the biologically active material is present in the struts and the non-structural elements (see [0057]). Shanley's non-structural elements are made of metal and formed integrally with the strut and as noted in section [0048] are non-deforming. The elements (14 and 30) of Shanley do not have any effect on the mechanical properties of the struts (18 and 20). Applicant traverses the 103 rejection of claim 11 because Shanley allegedly does not meet the limitations of claim 1. It is the examiners opinion that as the claims are currently written

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the limitations are met. Harish is used to teach that various drugs are well known in the art including the current drugs as claimed by applicant.

7. It is suggested that applicant amend the claims to more clearly point out the structure e.g. a region with non-structural elements that project between cross over points on the struts (see figures 6-9) or projects outward and away from the middle of the struts longitudinal portion as an example.

Conclusion

8. This is a continuation of applicant's earlier Application No. 10/062,794. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

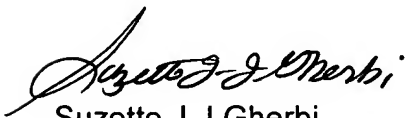
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the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

11. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J-J Gherbi
17 August 2005

FIG. 6

